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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,490	01/07/2002	Gavriel Meron	P-2038-US1	4535

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EXAMINER	
COUNTS, GARY W	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 05/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/036,490	MERON ET AL.	
	Examiner	Art Unit	
	Gary W. Counts	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/06/05*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-11,14-16,18-22,46 and 50* is/are pending in the application.

4a) Of the above claim(s) *23-44,47 and 48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-11,14-16,18-22,46 and 50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *02/01/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RD

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is vague and indefinite because it is unclear how a capsule is swallowable if it is attached to a needle or stent or endoscope. The specification on page 3 lines 27-30 discloses that the support can be attached to or can be an integral part of a medical device that can be inserted into body lumens, such as a stent, needle, or endoscope or a swallowable capsule. Please clarify.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-5, 7, 8, 14-16, 18-22, 46 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kovacs et al. (US 5,833,603) in view of Desai et al. (US 5,362,478).

Kovacs et al discloses an implantable biosensing transponder comprising a biosensor which may sense optical, mechanical, or chemical properties. The device also includes a transponder for wirelessly transmitting data corresponding to the sensed parameter to a remote reader. Disclosed embodiments use chemical sensors and pressure sensors (abstract). Nearly any type sensor can be used with the transponder of the reference, and the transponder can be used to measure a variety of parameters, including blood chemistry, such as sugar and hemoglobin levels (col. 3). The biosensor may be completely positioned within a capsule (Col. 4). In one embodiment, the transponder includes photosensors for optically detecting physical properties at the implant site. The biosensor may comprise an array of photosensors, such as an

imager, for providing an image of the implant site. Biosensng transponders using photosensors can also include one or more optical emitters for illuminating the implant site with specific wavelengths of light. For example, chemical sensitive dyes may be illuminated to detect a change in an optical property of the dye to detect a physical property of the external environment. The capsule may be implanted in contact with tissue or blood. Another dye of the same type of dye as is located on the exterior of the capsule is located within the capsule. The capsule is constructed from transparent glass. An optical emitter illuminated the dyes and causes them to emit fluorescence, and photosensors detect the optical properties of the dyes upon illumination. Dye on the outside of the capsule interacts with the environment to produce an optical change, which can be compared to dye within the capsule (Col. 10) Photosensors can also be used for direct optical sensing of the environment, such as for determining color of an organ (Col. 11).

Kovacs et al fail to specifically teach a swallowable capsule or a plastic support.

Desai et al. teach magnetic resonance imaging with fluorocarbons encapsulated within a polymeric shell. A suspension of polymeric shells can be administered intravenously or orally, and can facilitate optical imaging of the organ to which they are directed. The capsules of the reference can be used to obtain local oxygen or temperature data. Magnetic resonance imaging is used to illuminate the polymeric shells, and allows the determination of the location of shells, as well as the parameter of interest.

It would have been obvious to one of ordinary skill in the art to use a swallowable capsule as taught by Desai et al. for encapsulating the biosensing transponder of Kovacs et al. because Desai et al. teach the use of a swallowable capsule directed to a particular location for imaging and Kovacs teach that their transponder may be completely packaged within a capsule. Kovacs et al. also teach taught any sensor can be used and is only limited by the size of the sensor and space at the location. As such, one would have a reasonable expectation of success in using a sensor of dimensions appropriate to fit within a swallowable capsule while still achieving the results of Kovacs transponder. It would have also been obvious to use plastic as the support material with the device of Kovacs and Desai because any transparent material would have worked with the optical sensor of Kovacs. In addition, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin,* 125 USPQ 416.

7. Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kovacs et al. and Desai et al in view of Atarashi et al. (US 6,162,469)..

See above for the teaching of Kovacs et al and Desai et al.

Kovacs et al and Desai et al. differ from the instant invention in failing to teach a biological reactant.

Atarashi et al. teach a medical powder which comprises polymeric microspheres having thereon immobilized antigen or antibody for detection or diagnosis purposes. The powder may be used in vivo.

It would have been obvious to one of ordinary skill in the art to use a biological compound as the reactant as in Atarshi et al. on the support of Kovacs et al. because Atarashi et al. teach that biological compounds bound to supports may be used in vivo further, depending on the analyte of interest, one of skill in the art could have used its appropriate receptor with a reasonable expectation of success that it would function in a manner similar to the dye of Kovacs et al. In addition, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin,* 125 USPQ 416.

Response to Arguments

8. Applicant's arguments filed 12/06/04 have been fully considered but they are not persuasive.

Applicant argues that neither Kovacs nor Desai show a suggestion or motivation to modify the references or to combine references teachings. And Furthermore, at the time the invention was made there was no motivation or suggestion in the art to combine the non-mobile, implantable transponder of Kovacs with the swallowable capsule of Desai. This is not found persuasive because as stated in the previous office action Kovacs et al. specifically teaches that their transponder may be completely packaged within a capsule and Desai et al teach a capsule for enclosing compositions. Further, an autonomous swallowable capsule is intended use of the system and the Kovacs transponder is capable of being swallowed and passed through the digestive system and thus is capable of being an autonomous swallowable capsule.

Applicant further argues that the combination of Kovacs and Desai would yield and inoperable device because an attempt to swallow the Kovacs capsule, instead of implanting it, could make the Kovacs capsule inoperable, because an operator may not know the exact location of the Kovacs capsule (once it is swallowed) in order to radiate energy toward it. Applicant further states that Kovacs is in fact detrimental, to the operation of the in-vivo device of the claimed invention. This is not found persuasive because the arguments of counsel cannot take the place of evidence in the record. *In re Schulze,* 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965) (see MPEP 716.01(c)).

Applicant further argues that although Desai teaches a capsule which may be swallowed, Desai clearly does not teach a swallowable capsule having the type, the features of the characteristics of the in-vivo imaging capsule of the claimed invention. This is not found persuasive because the Examiner has not relied upon Desai for teaching the features to which Applicant refers. Examiner has relied upon Kovacs for teaching the features of the system and for the specific teaching that the system can be encapsulated.

Applicant further argues that it is improper to consider Desai as being relevant prior art. This is not found persuasive because Desai et al. teaches capsules for imaging sensors and Kovacs et al. teaches a biosensor which can be completely positioned within a capsule. Further, as stated above an autonomous swallowable capsule is intended use of the system and the Kovacs transponder is capable of being

swallowed and passed through the digestive system and thus is capable of being an autonomous swallowable capsule.

Conclusion

9. No claims are allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary Counts
Examiner
Art Unit 1641
May 9, 2005

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SUPERVISORY PATENT EXAMINER
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05/09/05